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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,375	06/09/2000	Keiji Endo	2173-0120P	2206

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EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/590,375	Applicant(s) Endo et al.
	Examiner Elizabeth Slobodyansky	Group Art Unit 1652

☒ Responsive to communication(s) filed on June 9, 2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) 7-9 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6, 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-10 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The preliminary amendment field concurrently with the specification amending claims 5, 7 and 10 has been entered.

Claims 1-10 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-6 and 10, drawn to a mutant α-amylase and a detergent composition comprising thereof, classified in class 510, subclass 226.

II. Claims 7-9, drawn to a DNA, a vector containing it, a cell comprising thereof and a method of use of said cell, classified in class 435, subclass 202.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because a protein and a DNA are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of invention II are not limited in use to the production of a mutant α-amylase of invention I and can be used as hybridization probes, and a mutant α-amylase of invention I can be obtained by a materially different method such as by the chemical synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. John Bailey on December 6, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6 and 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For the purposes of this examination the examiner consider the claim as reciting claim 2 or 3.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3 and 10 are confusing as reciting "residues respectively corresponding to ... in the amino acid sequence set forth in SEQ ID NO:1 in an α-amylase having said sequence in an α-amylase having said amino acid sequence" (emphasis added). While it is clear that residues in a sequence can correspond to the specific residues in SEQ ID NO:1, the residues of SEQ ID NO:1 are in SEQ ID NO:1, they do not correspond to themselves.

Claim 2 recites "residues from the amino terminal in the amino acid sequence set forth in SEQ ID NO:1". It is unclear which residues are encompassed by "the amino

terminal" versus the middle or the C-terminus. It is unclear what means "corresponding to 11 to 100 amino acid residues .... in SEQ ID NO:1" (see above). Amending to "a substitution of an 11 to 100 amino acid residues long fragment of SEQ ID NO:1", for example, is suggested. Further, the more conventional word in the art is "substitution" not "replacement".

Claim 5 is confusing because of at least of the following. It appears that on line 5 "with" should be replaced with ", wherein said mutant α-amylase has ...". It is unclear in which sequence the recited residues are present. Therefore, the insertion of " in SEQ ID NO:1" after "Gln" is suggested. As discussed above the use of "corresponding" with regard to the residues in the specific sequence is confusing. Further, "any one of claims 2 to 3" excludes "combined with each other".

In claim 6 reference to SEQ ID NO:1 should be given after the last recited position not after the 11th Tyr.

In claims 2-6, the use of "replacement of sequence" with regard to a fragment of sequence is confusing because "the sequence" is related to the entire sequence in the context of the claims.

Claim 10 is rejected as dependent from claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svendsen et al.

Svendsen et al. (US Patent 6,197,565) teach a mutant parent Termamyl-like α-amylase with improved properties over the parent amylase. They teach that Termamyl-like α-amylase is at least 60% homologous with *Bacillus* amylases such as *B. licheniformis* (column 3, lines 34-67). They teach the hybrid amylase wherein the N-terminal 35 amino acid residues (of the mature protein) of *B. licheniformis* α-amylase (SEQ ID NO:4) are replaced with the N-terminal 33 amino acid residues of *B. amyloliquefaciens* α-amylase. They teach the modified residues at the following positions in SEQ ID NO:4 that are important for stability: fragment 185-209 (column 8), residue 190 and residue 205 (claims 8 and 9). They teach the detergent compositions comprising the mutant amylases (column 14, line 65).

SEQ ID NO:1 of the instant invention is more than 60% identical to the sequence of *B. licheniformis* α-amylase. It would have been obvious to one of ordinary skill in the

art at the time the invention was made to make mutations in SEQ ID NO:1 at positions 190, 205 and 209 corresponding to positions 190, 205 and 209 in *B. licheniformis* α-amylase. It would have been further obvious to one of ordinary skill in the art at the time the invention was made to make a hybrid amylase wherein an N-terminal fragment is replaced with a fragment from another amylase. The motivation is provided by Svendsen et al. who teach mutant amylases with improved properties.

Claims 1, 2, 4-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchinson et al.

Mitchinson et al. (US Patent 5,736,499) teach importance of residue 188 in *B. licheniformis* α-amylase for thermostability (column 4, lines 47-56, claim 1).They teach the detergent compositions comprising the mutant amylases.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to mutate SEQ ID NO:1 at position 188 corresponding to position 188 in *B. licheniformis* α-amylase.

Claims 1, 2, 4-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al.

Suzuki et al. (form PTO-1449 file November 13, 2000) teach importance of residue 178 in *B. licheniformis* α-amylase for thermostability (e.g., abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to mutate SEQ ID NO:1 at position 178 corresponding to position 178 in *B. licheniformis* α-amylase.

Claims 1, 2, 4-6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Declerck et al.

Declerck et al. teach importance of residue 209 in *B. licheniformis* α-amylase for thermostability.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to mutate SEQ ID NO:1 at position 209 corresponding to position 209 in *B. licheniformis* α-amylase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner